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Subject Environmental Defense comments on 2-Ethylhexanol
Heavies (CAS# 68609-68-7)

(Submitted via Internet 6/6/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,
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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **2-Ethylhexanol Heavies (CAS# 68609-68-7)**.

The test plan and robust summaries for 2-ethylhexanol heavies was submitted by BASF Corporation. This substance is the high boiling fraction formed during the manufacture of 2-ethyl-1-hexanol. It is abbreviated as EP-204 and is similar in composition to Oxoel 800 which is made using a similar process in Germany.

According to the test plan, EP-204 is used primarily as a fuel for heat, in ore flotation applications and as a solvent, but no further details are provided so it is difficult to assess the opportunities for environmental and human exposures. However, the generalized uses and applications indicated for EP-204 and Oxoel 800 would likely lead to both environmental and human exposures. If the sponsor has information on environmental releases, it would be helpful to include such data in a revised submission.

EP-204 is comprised of at least 11 constituents, including alcohols, diols, alkylethers, alkyl esters, aliphatic hydrocarbons, aliphatic aldehydes and aliphatic acetals. Thus EP-204 is a complex mixture and the test plan provides considerable detail on the chemistry and composition of EP-204.

Although there are very few available data on SIDS endpoints for the EP-204 mixture, the sponsor contends that no additional studies are needed because some data are available for some of the individual constituents. While this contention may be valid for some of the physicochemical and environmental fate endpoints, satisfying the requirements for the toxicity endpoints requires that testing be done on the mixture itself.

Therefore, we disagree that no new studies are required and we recommend that the sponsor conduct a combined repeat dose/reproductive/developmental toxicity study and a genetic toxicity study on a representative sample of EP-204. Further support for this recommendation is as follows:

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1. Repeat dose data are available for only three of the constituents (2-ethylhexanol, 2-ethyl-1'3-hexanediol and 2-ethylhexanal), and these proposed surrogates are hardly representative of the variety of structures and functional groups contained in EP-204.
2. The pattern of toxicities caused by the many and varied constituents may not be captured by the proposed surrogates and the toxicity of the mixture may be greater than the sum of the individual constituents.
3. The sponsor argues that all of the constituents share common metabolic pathways. This is not supported, as complete metabolic pathways and metabolite identifications are not provided. In addition, the metabolites formed are different for many of the constituents, although they are formed in some cases by the same or similar enzymatic pathways. Just because a group of chemicals are oxidized and or conjugated does not mean that they will cause the same pattern of toxicities, as evidenced by a vast body of scientific literature; i.e., estrogens and polycyclic aromatic hydrocarbons.
4. Reproductive and developmental toxicity studies are available for only two of the constituents, and effects are observed on testes and ovarian weights.
5. Genetic toxicity data are available for five of the constituents, and some positive results were observed. Therefore, the EP-204 mixture should be tested for genetic toxicity.

Daphnia toxicity data are available for EP-204, although there are no data on this mixture in fish and algae. However, there are considerable data on seven of the individual constituents, the sponsor did estimate ecological toxicity of the mixture itself and there are data in Daphnia to indicate that the toxicity of the mixture is not greater than the sum of the individual constituents. Therefore, ecological toxicity tests on EP-204 may not be needed.

Thank you for this opportunity to comment.

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